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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,118	10/30/2001	Stanford Mark Moran	BMED-004/01US	8022

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EXAMINER
ANDRES, JANET L

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 07/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	10/004,118	MORAN, STANFORD MARK	
	Examiner	Art Unit	
	Janet L. Andres	1646	

-- The MAILING DATE of this c mmunication appears on the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *copy of facsimile transmission* .

DETAILED ACTION

Election/Restrictions

1. In a telephone conversation with Thomas Moran on June 22, 2003, Mr. Moran stated that, while the Examiner had previously agreed to accept a supplemental response to the restriction requirement of paper no. 5, an action on the first response was mailed. The error occurred because the supplemental response was not received by the Examiner, although Applicant's representative has provided facsimile evidence (copy attached) that it was in fact sent to the PTO. Regardless, all claims are rejoined and an action on claims 1-64 follows. The action as it pertains to claims 55-64 is identical to that of paper no. 8.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 41-64 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 079 405 A1, Corless et al., published 1983, and U.S. patent 5429602, Hauser, 1995.

Corless et al. teaches an infusion system comprising a controller that controls two pumps, one used for insulin and one for dextrose, on p. 9, line 39 and p. 10, lines 1-6. The pump rates can be altered; see p. 10, lines 29-39. Thus, Corless et al. teaches a system comprising two long-term delivery devices that can deliver drugs at constant rates, and those rates can be set to be different, anticipating the limitations of claims 41and 55. This system could also be used to deliver the same drug at different rates. That Corless et al. teaches the delivery of two

compounds does not change the nature of the device itself. Since the rates can be changed, the system taught by Corless et al. also anticipates the limitations of claims 42 and 56. The instructions of claims 43 and 57 constitute and intended use and do not alter the nature of the device itself; thus this claim is also anticipated by Corless et al. While claims 44-54, 58, 59, and 62-64 specify that the drug be an interferon, the nature of the drug to be delivered does not, as is stated above, change the nature of the device itself. The device taught by Corless et al. could also be used to deliver interferon and thus it meets the limitations of these claims. The diseases to be treated, specified in claims 47-54 and 60-64, are similarly an intended use of the device and do not change the nature of the device itself.

Hauser also teaches an infusion pump system that comprises two pumps. See column 2, lines 14-45. The infusion rates are separately programmable; see column 7, lines 17-38. Thus, for the reasons set forth for Corless et al. above, Hauser anticipates the limitations of claims 41-64.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-3, 8, 10, 14-19, 21-24, 28, 30, and 34-40 rejected under 35 U.S.C. 103(a) as being unpatentable over Palmeri et al. (J. Chemotherapy 1990, vol. 2(3), pp. 327-330) in view of EP 0 079 405 A1 and U.S. patent 5429602.

Palmeri et al. teaches administration of interferon α2a to patients suffering from colon cancer. Palmeri et al. teaches on p. 329, table 3, that interferon was administered at different levels to groups of three patients and that the dose was reduced for patients that exhibited fever (p. 328, column 2). Palmeri et al. fails to teach the use of controlled-release formulations. EP 0 079 405 A1 and U.S. patent 5429602 teach devices suitable for controlled release, as set forth above. It would be obvious to one of ordinary skill in the art to combine the teachings of Palmeri et al. with those of EP 0 079 405 and the '602 patent to use administer a controlled-release dose of interferon α2a over the short term, evaluate side effects, and adjust the dose accordingly for long-term use. One of ordinary skill would be motivated to do so because Palmeri et al. teaches the necessity of optimize interferon α2a levels for long term use and EP 0 079 405 A1 and the '602 patent teach methods for administering prescribed doses at different levels over periods of time. One of ordinary skill would thus expect the devices of EP 0 079 405 A1 and the '602 patent to be useful in an optimization scheme. Thus Palmeri et al., EP 0 079 405 A1 and the '602 patent render obvious the limitations of claim 1. Palmeri et al. teaches administration of interferon α2a at three different levels (table 3, p. 329). Palmeri et al. further teaches the identification of an optimum dose based on this approach on p. 330, column 1. Thus claims 21-24 are unpatentable over Palmeri et al. in view of EP 0 079 405 A1 and the '602 patent. Claims

2 and 3 are similarly rendered obvious because Palmeri et al. teaches both humans and interferon α. Since the same interferon and formulation is used for both short and long term in Palmeri et al., the limitations of claim 8, 10, 28, and 30 are also obvious. Palmeri et al. additionally teaches administration of the short-term dose first and teaches both dose alteration and dose maintenance after the administration of the short-term does, rendering claims 14-16 and 34-36 obvious. The devices of EP 0 079 405 A1 and the '602 patent meet the limitations of claims 17-19 and 37-40, thus rendering those claims unpatentable.

Thus, Palmeri et al. teaches a method of dose optimization meeting the limitations of Applicant's claims, and EP 0 079 405 A1 and the '602 patent teach devices for controlled delivery meeting the limitations of Applicant's claims. It would be obvious to one of ordinary skill in the art to use the devices taught by EP 0 079 405 A1 and the '602 patent in the methodology taught by Palmeri et al. because, as set forth above, one of ordinary skill would recognize that such devices would provide the means to administer and optimize doses, and Palmeri et al. teaches that such administration and optimization is beneficial.

6. Claims 4-7, 9, 12, 13, 20, 25-27, 29, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmeri et al., EP 0 079 405 A1, and U.S. patent 5429602 in view of Johnson et al. (Scientific American, May 1994, pp. 68-75).

Palmeri et al., EP 0 079 405 A1, and the '602 patent teach as set forth above but fail to teach the interferons, formulations, or diseases meeting the limitations of these claims. Johnson et al. teaches that interferons may be used to treat hepatitis B and C, Kaposi's sarcoma, hairy-cell leukemia, chronic granulomatous disease, and multiple sclerosis, as specified in claims 4-7 and 25-27 (p. 74). Johnson et al. also teaches that interferon ω is related to interferon α and β (p. 70)

and thus one of ordinary skill would expect it to have similar functions and side effects. It would be obvious to one of ordinary skill in the art to combine the teachings of Palmeri et al., EP 0 079 405 A1, and the '602 patent with those of Johnson et al. to optimize doses for treatment of other disease. One of ordinary skill would be motivated to do so because Palmeri et al. teaches that interferon α a2 has toxic side effects and provides means to minimize them, and Johnson et al similarly teaches on p. 72 that interferons α, β, and γ have serious side effects that limit their use. Neither Palmer et al. nor Johnson et al. teach the combination of different interferons. However, it would be obvious to one of ordinary skill in the art to use different interferons that act similarly for the same purpose, as is claimed in claims 9, 12, 13, 29, 32, and 33. One of ordinary skill would be motivated to do so because Johnson teaches that related interferons have similar effects (p. 70); the motivation to combine them arises from their common purpose. See *In re Kerkhoven* (205 USPQ 1069, CCPA 1980):

> "It is *prima facie* obvious to combine two compositions each of which is taught by prior art to be useful for the same purpose in order to form a combination that is to be used for the very same purpose: the idea of combining them flows logically from their having been individually taught in the prior art."

7. Claims 11and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmeri et al., EP 0 079 405 A1 and the '602 patent in view of U.S. patent 4847049 (Kwan, 1989).

None of the references cited in paragraph 7 above explicitly teach administration in different formulations. However, the devices of EO 0 079 405 A1 and the '602 patent allow for the independent administration of two different factors. The '049 patent teaches a pharmaceutical composition of interferons that retards microbial growth for longer than four weeks (column 2). The '049 patent additionally teaches the advantages of such compositions for administration over extended times. It would be obvious to one of ordinary skill in the art to

combine the teachings of the '049 patent with those cited above to use this formulation in combination with other formulations. One of ordinary skill in the art would have been motivated to do so because Palmeri et al. teaches short-term treatment followed by long-term treatment, and the devices of EO 0 079 405 A1 and the '602 patent allow for the use of different formulations. Thus one of ordinary skill would readily appreciate that two different formulations could be used for the two different terms taught by Palmeri et al.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to **[yvonne.eyler@uspto.gov]**.

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly

set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
Patent Examiner
July 11, 2003